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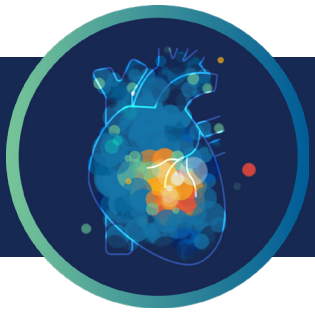
EXPERT INSIGHTS: Q&A WITH PROF. STEFAN JAMES



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Access the full publication: **Preventive percutaneous coronary intervention versus optimal medical therapy alone for the treatment of vulnerable atherosclerotic coronary plaques (PREVENT)**

In plain language, how would you summarize the findings from this trial to a patient with stable atherosclerotic cardiovascular disease in your clinic?

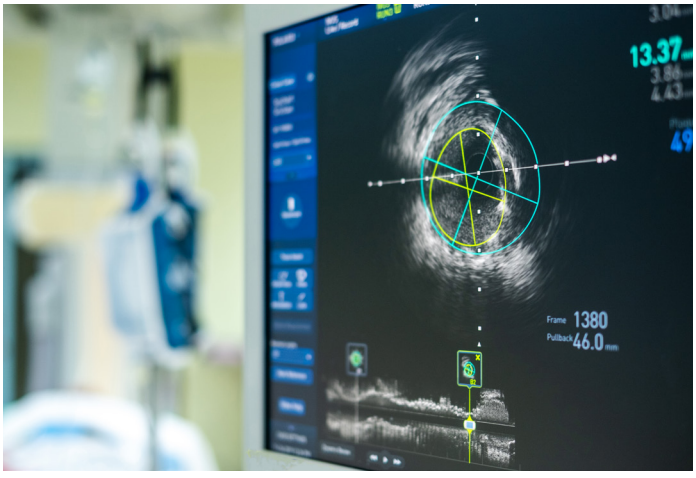
Non-flow-limiting coronary lesions are very common among patients with coronary disease and vulnerable plaques can be detected in about half of these lesions. These findings suggest that many patients are at risk for future cardiovascular events and that long-term secondary preventive therapy is important. Whether or not these vulnerable plaques should be intervened upon is still an unresolved question. This trial suggested that preventive stenting reduced the risk of future coronary clinical events as compared to medical therapy. However, the difference in favor of preventive stenting was largely driven by hospitalization for unstable angina and to some degree by ischemia driven target vessel revascularization. In an open label trial these findings are prone to a biased assessment and we need to be careful whether to interpret this as a true benefit of the preventive revascularization procedure. The study will not change my clinical practice but the trial provides compelling data that should stimulate further studies.

This study adopted an open-label design, which exposes the trial to potential bias. Do you think a sham-controlled, single-blinded study design may have lent greater validity to the study's findings?

Yes, the open label design is a clear limitation to the interpretation of the data. Sham controlled trials are very difficult to do but could provide more reliable evidence. A much larger study that can collect a sufficient number of hard clinical endpoints would also be able to confirm the interesting findings from the PREVENT trial.

Given that just 6-7% of the randomized cohort had thin-cap fibroatheroma noted on optical coherence tomography or radiofrequency intravascular ultrasound, do you think the vulnerable coronary plaques treated in the PREVENT trial were "vulnerable" enough?

The investigators used reasonable criteria for plaque vulnerability but most of the patients were defined with vulnerability based on minimal lumen diameter and plaque burden rather than thin cap fibroatheroma. Plaque vulnerability is of course relative and a higher degree of vulnerability may have been found had they enrolled more ACS patients at higher risk.



One could argue the results of this study are not generalizable enough given the recruitment of subjects restricted to the Asia-Pacific region, relatively low female representation and the early use of bioresorbable vascular scaffolds for stenting of vulnerable plaques. What further evidence is required in your view, before preventive percutaneous coronary intervention (PCI) of vulnerable atherosclerotic plaque could become prime time?

I am not too concerned about the geographical generalizability. Patients outside the Asian Pacific region are often at higher risk. A larger trial less prone to bias, with more hard clinical events or using sham control and blinded outcomes assessment is needed before we should embrace preventive interventions due to potentially higher risk and higher costs and perhaps less interest in medical and lifestyle treatment.

Given the emergence of PCSK9-targeted therapies, encouraging results from trials of a novel CETP inhibitor, large scale cardiovascular outcomes trials of lipoprotein(a) lowering and guideline-directed management of coronary inflammation, do you think there will be a place for preventive PCI of vulnerable plaque in the future?

Often a combination of therapies is needed. Patients may have different preferences; therapeutic options are associated with different risks and cost and often multiple targets are needed. Primary and secondary lifestyle measures should never be underestimated or forgotten.